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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,834	02/13/2002	Johannes Booij	246152015300	5546

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EXAMINER

BERCH, MARK L

ART UNIT PAPER NUMBER

1624

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/937,834	Applicant(s) BOOIJ ET AL.	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2004.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,12-14,16-20,27,28,31,34-37,39-44,47-51 and 54-60 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 10,12-14,16-20,27,28,31,34-37,39-44,47-51 and 54-60 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>10/20/04</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/25/04 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 12-14, 16-20, 27-28, 31, 34-37, 39-44, 47-51, 54-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Contacting is step (a) makes no sense, since as written, it does not say what the potassium clavulanate is being contacted with. Suggested is "dissolving".
2. The term "non-agglomerate crystals" (third from last line of claim 10) is indefinite as it is self-contradictory. Crystals are agglomerates by their very nature.

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3. Likewise, the phrase, “an agglomerate comprising potassium clavulanate” is indefinite. This clearly excludes forms of potassium clavulanate which are non-agglomerated, but where is the line between agglomerate and non-agglomerate? The specification does not provide any clear guideline.
4. Claim 13 has puzzling wording. It begins by setting forth three possibilities: a) water b) ethanol and c) mixture of water and ethanol. But then it requires “water is present in said mixture.” How could water not be present, since the mixture is defined as water and ethanol? What is the purpose of the last phrase?
5. The use of “comprising” is improper for Markush groups (as in claim 57, 59). See MPEP 2173.05(h).

Claims 10, 12-14, 16-20, 27-28, 31, 34-37, 39-44, 47-51, 54-60 are rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Specifically:

The process is not described properly. They fail to particularly point out and distinctly claim the actual process (paragraph 2). They are not enabled for the broad scope as written (paragraph 1).

As written, this is a very broadly defined process which dissolves the potassium clavulanate in any solvent, and precipitates it by means of any anti-solvent. However, such a procedure is set forth in the prior art as giving either needles or the rosette-like form, which is exactly what the claims exclude. See USP 5288861 (Clark) which teaches exactly that. Thus, this reference is evidence that such scope as is claimed is

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not enabled, since Clark uses a process easily within the claim 10 language, and yet does not give the claimed product. When operativeness has been properly challenged, it is incumbent on applicant to limit the claims accordingly, cf. *In re Harwood*, 156 USPQ 673, *In re Cook*, 169 USPQ 298, *In re Langer*, 183 USPQ 288, *In re Corkill*, 226 USPQ 1005, 1009, and *In re Rainier*, 153 USPQ 802. MPEP 2164.08 states, "The Federal Circuit has repeatedly held that 'the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." The full scope is clearly not enabled, since Clark's procedure will not give the right product. As another example, Taskis (see ex 4) produces needles from a methanol solvent and a dichloromethane antisolvent.

Alternatively, the claims do not particularly point out and distinctly claim the actual process that does produce the non-needle, non-rosette form actually produced. That is, it is written so generically that it embraces both the process that does give the required product, and the process which does not.

The matter is considerably exacerbated by the fact that the e.g. Clark process and that of applicants are so very similar. Both use aqueous solvent for the potassium clavulanate, and acetone as antisolvent. Thus, there are no clear guidelines as to how to avoid the needles/rosette form. That is, the specification simply says that one gets a different product, without saying what one does differently to get that different product, and the claims do not have any such differentiation either.

Claims 10, 12-14, 16-20, 27-28, 31, 34-37, 39-44, 47-51, 54-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description

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requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specification, page 5, lines 26-27 requires that at least one of the solvents has to be water. All claims fail to so require, and thus read on processes which do not have water present in the solvent, which is broader than what the specification sets forth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37, 40-42, 44, 46-51, 58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 4454069, 6417352, 5288861, US 20030022882 A1, 5985625, or WO 98/21212.

In 4454069, see column 5, lines 36-39, which refers to Potassium clavulanate in the form of “microcrystals ... well-defined needles or waisted plates.” The latter form would avoid the provisos of the claim. The reference states that the product of this invention is “produced in pure form in large crystals which may be well-defined needles or waisted plates (i.e. butterfly-shaped)”. Those plates are thus presumed to be the result of examples 3 or 4. 6417352 gives another crystallization. The form is not stated, but conditions which would be expected to obtain the rosettes were not used. In

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US 20030022882 A1, in example 4 and in 5985625, example 3, see the product formed in isopropanol. Applicants argue that needles would be expected, but give no reasoning, and the examiner notes that the method language in the claim is so broad as to embrace procedures that would produce needles anyway. In 5288861, a description of different forms ("rod-like" and "plate-like crystals") appears at column 1, lines 41-45. In WO 98/21212, see example 6.

With regard to 6417352, it is correct that the reference is silent on the matter of its e.g. density characteristic, and 4454069 is silent on the particle size characteristic. However, if mere silence were enough, then every anticipation could be overcome by simply putting in some limitation that the reference happened to be silent about, even if the material were exactly the same as the prior art. One could put in a limitation about density, color, melting point, solubility in some obscure solvent, spectroscopic data, and then simply point to the silence of the reference, as applicants have done here. Applicants could insert the limitation "which does not explode upon tapping" and point out the reference says nothing about this limitation at all.

MPEP 2112 states: "A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC"

The section goes on as follows:

"Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best, 562 F.2d 1252, 1255 n.4, 195

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USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims."

Here, the "function is not explicitly disclosed by the reference" is the compressibility, etc. Applicants need to show that such is not actually present in the reference.

Applicants have added product-by-process limitation, which limitation these references do not meet. In product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). See also *In re Hirao*, 190 USPQ 15 (footnote 3); *Ex parte Edwards*, 231 USPQ 981; *In re Pilkington*, 162 USPQ 145, 147; *In re Dilnot*, 133 USPQ 289. Thus, a rejection is proper over a prior art reference which shows the same product, even if made by a different process.

Claims 37, 39-44, 46-52 are rejected under 35 U.S.C. 102(b) as being anticipated by WO97/33564.

In WO97/33564, see the agglomerate at page 10, lines 13-23, and examples 7-11. Other particle size distributions appear at page 5-6. Potassium clavulanate in crystalline form may be presumed, since it is generally available in that form. Page 10 says, "Mixtures of agglomerates of a p-lactam antibiotic such as amoxicillin trihydrate with a second pharmaceutically active agent, e.g. potassium clavulanate...." Examples 7-11 all

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have Potassium clavulanate in the agglomerate. The traverse, based on the different method, is unpersuasive. Much the same reasoning applies here.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 12-14, 16-20, 27-28, 31, 34-37, 42-44, 47-51, 54-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Box.

See example 4. The Na salt was prepared, and the solution evaporated. This material was recrystallized from water-acetone. Since clavulanates are water soluble, but insoluble in acetone, water is the solvent, and acetone the antisolvent. The sole difference is that applicants do this on the K salt, whereas the example has the Na. However, the reference makes it clear that this procedure can be used on the K salt as well; see e.g. claim 3.

The response from applicants included an "Exhibit 1" but the remarks do not appear to address this document.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571)272-0674. If you are unable to reach

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Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at 571-272-0661. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

A handwritten signature in black ink, appearing to read "Mark L. Berch", with a stylized, flowing script.

Mark L. Berch
Primary Examiner
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November 30, 2004